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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,075	02/19/2004	Sean D. Monahan	Mirus.030.16.6	4417

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EXAMINER	
CHONG, KIMBERLY	
ART UNIT	PAPER NUMBER
1635	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/782,075	MONAHAN ET AL.	
	Examiner	Art Unit	
	Kimberly Chong	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-10,13 and 14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-10,13,14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed 10/08/2007 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 07/11/2007 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

With entry of the amendment filed on 10/08/2007, claims 1, 4-10 and 13-14 are pending in the application. Applicant has canceled claims 2-3 and 11-12.

Response to Declaration

The declaration filed on 10/08/2007 under 37 CFR 1.132 is sufficient to overcome the rejection of claims 1, 4-6 and 13-14 based upon the 35 U.S.C. 102(b) rejection as being anticipated by Bennett et al. (U.S. Patent No. 6,008,344) and the rejection of claims 1, 4-10 and 12-14 based upon the 35 U.S.C. 103(a) rejection as being unpatentable over Bennett et al. (U.S. Patent No. 6,008,344), Tuschl et al. (cited on PTO form 892 filed 11/29/2005), Hammond et al. (Nature, 2001; Vol. 2, 110-119) and Goldsborough (cited on PTO form 892 filed 11/29/2005) and as evidenced by Letsinger et al (PNAS 1989).

New Claim Rejections

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4-10, 13 and 14 are provisionally rejected under the judicially created doctrine of double patenting over claims 1, 3, 6-7, 10-18 of copending Application No. 10/780,484. This is a provisional double patenting rejection since the conflicting claims have not yet been patented. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of the patent are drawn to patently indistinguishable subject matter.

The instant claims are drawn to a composition comprising a modified RNA and a transfection reagent wherein said modified RNA consists of a functional group post-synthetically linked to a RNA via a labile bond cleavable under mammalian physiological conditions and wherein the modified RNA is a siRNA.

Claims 1, 3, 6-7, 10-18 of copending Application No. 10/780,484 are drawn to a composition for delivering a polynucleotide to a mammalian cell comprising membrane active polyamine and wherein the polynucleotide is a dsRNA, siRNA or antisense or ribozyme molecule an wherein the polyamine is linked to the polynucleotide via a labile covalent bond. The specification of copending Application No. 10/780,484 teach siRNA can me modified at the 2' position (see paragraph 0048), teach more than one functional group can be linked via labile bonds (see paragraph 0010) and teach the siRNA can comprise silylated, acylated or alkylated RNA (see paragraph 0027).

Claims 1, 3, 6-7, 10-18 of the instant copending application are drawn to a polyamine membrane active compound which is a species of the instantly claimed genus of functional groups attached to a modified RNA. Thus, claims 1, 3, 6-7, 10-18 of the instant copending application anticipate the genus of claims 1, 4-10, 13 and 14 of the instant application. This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 5, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Wolff et al. (US 2001/0044417).

The instant claims are drawn to a composition comprising a modified RNA and a transfection reagent wherein said modified RNA consists of a functional group post-synthetically linked to an RNA via a labile bond cleavable under mammalian physiological conditions and wherein said functional group enhances interaction of said RNA with said transfection reagent, wherein the modified RNA is more resistant to nucleases and wherein a plurality of functional groups are attached to said RNA via labile bonds.

Wolff et al. teach a composition comprising a polymer and a polynucleotide, such as an RNA or antisense compound (see paragraph 0120-0121) wherein the polymer is attached to the polynucleotide via a disulfide bond wherein the disulfide bond is cleavable under physiological conditions in a cell (see paragraph 0117). Wolff et al. teach the antisense RNA can be modified comprising chimeric sequences or contain different backbones and bases (see paragraph 0120). Wolff et al. teach the linked polymer can be targeting groups, reporter or marker molecules, steric stabilizers or polycations, for example (see paragraph 0103) and teach the composition comprises more than one functional group attached via disulfide bonds (see paragraph 0012-0014).

Thus Wolff et al. anticipates claims 1, 5, 13 and 14 of the instant application.

Claims 1, 4-6, 10 and 13-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Lewis et al. (US 2003/0143204).

The instant claims are drawn to a composition comprising a modified RNA and a transfection reagent wherein said modified RNA consists of a functional group post-synthetically linked to an RNA via a labile bond cleavable under mammalian physiological conditions and wherein said functional group enhances interaction of said RNA with said transfection reagent and further wherein the function group is lined the 2'-hydroxyl ribose position, wherein the modified RNA is more resistant to nucleases and wherein a plurality of functional groups are attached to said RNA via labile bonds.

Lewis et al. teach compositions comprising RNA compounds such as siRNA or antisense wherein the antisense compounds comprise 2'- modifications (see paragraph 0042). Lewis et al. teach the RNA compounds are attached to functional groups used to aid in the delivery of the RNA compound to the cell as well as stability of the complex and teach when attached to functional groups, the functional group alters the interactions of the complex to the attached group and teach such functional groups are cell targeting compounds, lipids and carbohydrates (see paragraph (0112) and further teach multiple functional groups can be attached (see paragraph 0032). Lewis et al. teach the functional groups are attached via labile bonds that can be selectively broken and dissociated to provide an active inhibitor in the cell (see paragraphs 0120-0128).

Thus, Lewis et al. anticipates claims 1, 4-6, 10 and 13-14 of the instant invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4-9, 13 and 14 rejected under 35 U.S.C. 103(a) as being obvious over Hughes et al. (U.S. Patent No. 6,169,078), Manoharan, M. (Biochimica et Biophysica Acta 1489, 1999: 117-130) and Goldsborough (of record PTO Form 892 11/29/2005).

The instant claims are drawn to a composition comprising a modified RNA and a transfection reagent wherein said modified RNA consists of a functional group post-synthetically linked to an RNA via a labile bond cleavable under mammalian physiological conditions and wherein said functional group enhances interaction of said RNA with said transfection reagent, wherein the modified RNA is more resistant to nucleases and wherein a plurality of functional groups are attached to said RNA via labile bonds.

Hughes et al. teach liposome transfection reagents comprising a cationic lipid and a polynucleotide wherein the lipids attached to the polynucleotide via a disulfide bond wherein the disulfide bond is cleavable under physiological conditions in a cell (see column 4, line 50 to top of column 5, line 5). Hughes et al. teach the polynucleotide can be RNA (see column 2, lines 40-45) and teach the association of the two molecules achieves a stable association in an extracellular space (see column 4, lines 20-28). Upon entering the cytosol of the cell, the disulfide bond is broken and the

RNA polynucleotide is releases (see column 4, lines 26-29). Hughes et al. do not teach modified RNA such as silylated, acylated or alkylated RNA and do not teach attachment of the functional group to the ribose at the 2' hydroxyl position.

Goldsborough disclose the RNA can consist of a silylated RNA (see page 25), an acylated RNA (see page 20) or an alkylated RNA (see page 21). Goldsborough disclose the modified RNA consists of a functional group attached to a ribose 2'-hydroxyl position (see page 41), the modified RNA has more than one, but not all of the ribose 2-hydroxl positions modified (see page 13) and the modified RNA are more resistant to nucleases (see Example 61). Goldsborough disclose a modified RNA molecule comprising a functional group at the 2'-hydroxyl position (see page 21) and wherein the functional groups increases the RNA molecules stability which would enhance delivery of the RNA to a mammalian cell.

Manoharan et al. teach efficient conjugation of conjugates such as carbohydrates and other ligands at the 2' position of the RNA (see page 124).

It would have been obvious to incorporate modified silylated RNA, acylated RNA or alkylated RNA into RNA molecules, as taught by Goldsborough. It would have further been obvious to conjugate functional groups to RNA at the 2' hydroxyl position of the RNA, as taught by Manoharan.

One of skill in the art would have been motivated to incorporate modified silylated RNA, acylated RNA or alkylated RNA into RNA molecules because Goldsborough teach incorporating silylated RNA, acylated RNA or an alkylated RNA into a RNA molecule protects the RNA from degradation. Goldsborough teach RNA is inherently unstable

and protecting RNA from degradation while maintaining the biological activity of RNA is essential for use by one of skill in the art (see pages 3-4). Goldsborough et al. teach modified RNA molecules would have enhanced activity compared to natural RNA molecules because they are more stable and able to enter the cell more readily (see page 71). Further, one of skill in the art would have been motivated to attach the functional group to the 2' hydroxyl position of a RNA given Manoharan teach this position improves the chemical properties such as stability and nuclease resistance of said RNA molecules.

Finally, one would have a reasonable expectation of success because Goldsborough teach successful incorporation of a silylated RNA, acylated RNA or an alkylated RNA into a RNA molecule and further teach incorporation of such RNA does not affect the biological activity of the modified RNA. Moreover, one would have expected to conjugate a functional group to the 2' hydroxyl position of a RNA give Manoharan et al. teach efficient RNA molecules with enhanced properties when functional groups are attached at the 2' position.

Thus in the absence of evidence to the contrary, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1, 4-6, 10, 13 and 14 rejected under 35 U.S.C. 103(a) as being obvious over Wolff et al. (US 2001/0044417), Manoharan, M. (Biochimica et Biophysica Acta 1489, 1999: 117-130) and Tuschl et al. (of record PTO Form 892 11/29/2005).

The instant claims are drawn to a composition comprising a modified RNA and a transfection reagent wherein said modified RNA consists of a functional group post-synthetically linked to an RNA via a labile bond cleavable under mammalian physiological conditions and wherein said functional group enhances interaction of said RNA with said transfection reagent, wherein the modified RNA is more resistant to nucleases and wherein a plurality of functional groups are attached to said RNA via labile bonds.

Wolff et al. teach a composition comprising a polymer and a polynucleotide, such as an RNA or antisense compound (see paragraph 0120-0121) wherein the polymer is attached to the polynucleotide via a disulfide bond wherein the disulfide bond is cleavable under physiological conditions in a cell (see paragraph 0117). Wolff et al. teach the antisense RNA can be modified comprising chimeric sequences or contain different backbones and bases (see paragraph 0120). Wolff et al. teach the polymer can be targeting groups, reporter or marker molecules, steric stabilizers and polycations, for example (see paragraph 0103) and teach the composition comprises more than one functional group attached via disulfide bonds (see paragraph 0012-0014). Wolff et al. do not teach attachment of the functional group at the ribose 2' hydroxyl position nor teach the modified RNA is a siRNA or a micro RNA.

Tuschl et al. teach siRNA molecules and teach compositions comprising siRNA that are capable of silencing gene expression (see page 9, lines 17-25). Tuschl et al. teach that siRNAs represent a new alternative to antisense therapeutics.

Manoharan et al. teach efficient conjugation of conjugates such as carbohydrates and other ligands at the 2' position of the RNA (see page 124).

It would have further been obvious to conjugate functional groups to RNA at the 2' hydroxyl position of the RNA, as taught by Manoharan. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute a siRNA molecule, as taught by Tuschl et al. to attach a functional group via a labile bond to facilitate delivery of said siRNA to cells.

One of skill in the art would have been motivated to attach the functional group to the 2' hydroxyl position of a RNA given Manoharan teach this position improves the chemical properties such as stability and nuclease resistance of said RNA molecules. Further, one would have been motivated to use a siRNA instead of an antisense for gene targeting because it was well known at the time the invention was made that siRNA molecules are efficient molecules to target and decrease expression of a target gene and because siRNA has been proven to be more sequence specific than using antisense methodologies. One would have been motivated to attach functional groups to siRNA to facilitate delivery of said molecule to cells because siRNA, like antisense molecules, are susceptible to delivery problems and one would want to attach functional groups using labile bonds that are able to be targeting specifically to cellular compartments.

One would have a reasonable expectation of success at linking functional groups to siRNA given that Wolff et al. teach efficient conjugation of functional groups to inhibitory antisense RNA molecules. Moreover, one would have expected to conjugate

a functional group to the 2' hydroxyl position of a RNA give Manoharan et al. teach efficient RNA molecules with enhanced properties when functional groups are attached at the 2' position.

Thus in the absence of evidence to the contrary, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1, 4-10, 13 and 14 rejected under 35 U.S.C. 103(a) as being obvious over Fosnaugh et al. (US 2003/0143732), Manoharan, M. (Biochimica et Biophysica Acta 1489, 1999: 117-130) and Goldsborough (of record PTO Form 892 11/29/2005).

The instant claims are drawn to a composition comprising a modified RNA and a transfection reagent wherein said modified RNA consists of a functional group post-synthetically linked to an RNA via a labile bond cleavable under mammalian physiological conditions and wherein said functional group enhances interaction of said RNA with said transfection reagent, wherein the modified RNA is more resistant to nucleases and wherein a plurality of functional groups are attached to said RNA via labile bonds.

Fosnaugh et al. teach conjugates comprising siRNA and functional groups that are used to facilitate delivery of the siRNA into a biological system, such as cells (see paragraph 0172). Fosnaugh et al. teach the siRNA can be modified at the 2' hydroxyl position (see paragraph 0165) and teach the functional group are attached to the siRNA via biodegradable linkers wherein the linkers are degradable in biological systems i.e.

mammalian cells (see paragraph 0174). Fosnaugh et al. teach the functional groups can be lipids or peptides, for example (see paragraph 0175) and teach the conjugate can be mixed with transfection reagents for delivery to cells (see paragraphs 0193 and 0195). Fosnaugh et al. do not specifically teach attachment of the functional group at the 2' position of the ribose nor teach the modified siRNA comprising silylated, acylated or alkylated RNA.

Goldsborough disclose the RNA can consist of a silylated RNA (see page 25), an acylated RNA (see page 20) or an alkylated RNA (see page 21). Goldsborough disclose the modified RNA consists of a functional group attached to a ribose 2'-hydroxyl position (see page 41), the modified RNA has more than one, but not all of the ribose 2-hydroxl positions modified (see page 13) and the modified RNA are more resistant to nucleases (see Example 61). Goldsborough disclose a modified RNA molecule comprising a functional group at the 2'-hydroxyl position (see page 21) and wherein the functional groups increases the RNA molecules stability which would enhance delivery of the RNA to a mammalian cell.

Manoharan et al. teach efficient conjugation of conjugates such as carbohydrates and other ligands at the 2' position of the RNA (see page 124).

It would have further been obvious to conjugate functional groups to RNA at the 2' hydroxyl position of the RNA, as taught by Manoharan. It would have further been obvious to incorporate modified silylated RNA, acylated RNA or alkylated RNA into RNA molecules, as taught by Goldsborough. It would have further been obvious to conjugate

functional groups to RNA at the 2' hydroxyl position of the RNA, as taught by Manoharan.

One of skill in the art would have been motivated to incorporate modified silylated RNA, acylated RNA or alkylated RNA into RNA molecules because Goldsborough teach incorporating silylated RNA, acylated RNA or an alkylated RNA into a RNA molecule protects the RNA from degradation. Goldsborough teach RNA is inherently unstable and protecting RNA from degradation while maintaining the biological activity of RNA is essential for use by one of skill in the art (see pages 3-4). Goldsborough et al. teach modified RNA molecules would have enhanced activity compared to natural RNA molecules because they are more stable and able to enter the cell more readily (see page 71). Further, one of skill in the art would have been motivated to attach the functional group to the 2' hydroxyl position of a RNA given Manoharan teach this position improves the chemical properties such as stability and nuclease resistance of said RNA molecules.

Finally, one would have a reasonable expectation of success because Goldsborough teach successful incorporation of a silylated RNA, acylated RNA or an alkylated RNA into a RNA molecule and further teach incorporation of such RNA does not affect the biological activity of the modified RNA. Moreover, one would have expected to conjugate a functional group to the 2' hydroxyl position of a RNA give Manoharan et al. teach efficient RNA molecules with enhanced properties when functional groups are attached at the 2' position.

Thus in the absence of evidence to the contrary, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Applicant's Arguments

Re: Claim Rejections - 35 USC § 102

The rejection of claims 1, 4-6 and 13-14 under 35 U.S.C. 102(b) as being anticipated by Bennett et al. (U.S. Patent No. 6,008,344) is withdrawn in response to claim amendments filed 01/08/2007.

Re: New Claim Rejections - 35 USC § 103

The rejection of claims 1, 4-10 and 12-14 under 35 U.S.C. 103(a) as being unpatentable over Bennett et al. (U.S. Patent No. 6,008,344), Tuschl et al. (cited on PTO form 892 filed 11/29/2005), Hammond et al. (Nature, 2001, Vol. 2, 110-119) and Goldsborough (cited on PTO form 892 filed 11/29/2005) and as evidenced by Letsinger et al (PNAS 1989) is withdrawn in response to claim amendments filed 01/08/2007.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance.

Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

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KC
Examiner AU 1635

/Sean McGarry/

Primary Examiner

AU 1635